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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,922	07/09/2001	Amanda Johanne Kiliaan	BO 44633	5229

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EXAMINER
DAVIS, RUTH A

ART UNIT	PAPER NUMBER
1651	6

DATE MAILED: 02/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No. 09/899,922	Applicant(s) KILIAAN ET AL.	
	Examiner Ruth A. Davis	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *19-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☒ Claim(s) *1, 6 and 13* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's amendment filed January 7, 2002 has been received and entered into the case. Claims 1 – 25 are pending.

1. Applicant's election with traverse of Group I, claims 1 – 18 in Paper No. 5 is acknowledged. The traversal is on the ground(s) that the inventions are linked and are exactly coextensive in scope. This is not found persuasive because as stated in the previous Office action, the inventions are distinct and separate because the two groups require different searches. Moreover, a reference which would anticipate one invention may not anticipate or even make obvious another.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

2. Claims 1 and 13 are objected to because of the following informalities: In claim 1, the claim must end with a period. In claim 13, "gingko" should be spelled correctly as "ginkgo". Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1 – 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and its dependents are drawn to a method for preventing/treating vascular disorders however is rendered vague and indefinite for reciting "or equivalents thereof" because it is unclear what applicant regards as an "equivalent" of the instant ingredients. Moreover, applicant does not clearly set forth the scope of the limitation.

Claim 4 is rendered vague and indefinite for reciting "or an analog thereof" because it is unclear what is encompassed by the limitation of the claimed invention. Applicant does not define what is a "analog thereof", therefore the claim is unclear and confusing.

Claims 5 and 6 are unclear for reciting "Ω". Applicant may prefer to replace "Ω" with "omega" to more clearly define the invention.

Claim 11 is rendered vague and indefinite for reciting "or functional analogs thereof" because it is unclear what is encompassed by the limitation of the claimed invention. Applicant does not define what is a "functional analog thereof", therefore the claim is unclear and confusing.

Claim 11 is further confusing because it is unclear if "functional analogs thereof" refers only to coenzyme Q10, or to each carnitine, vitamin B1, B5 and coenzyme Q10.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the

explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, claim 14 recites the broad recitation "vitamin D", and the claim also recites "in particular vitamin D3" which is the narrower statement of the range/limitation.

Claim 16 recites the broad recitation "at least X", and the claim also recites "preferably at least Y" which is the narrower statement of the range/limitation.

Claim 18 recites the broad recitation "related disorders", and the claim also recites "particularly X" which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1 and 5 – 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sagami Chem Res Centre (1998), Horrobin (1996) and Hashim (1995).

Applicant claims a method for treating and/or preventing vascular disorders and/or secondary disorders associated therewith, the method comprising administering a composition comprising (a) long chain polyunsaturated fatty acids, (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine and (c) one or more compounds selected from folate, vitamin B12, B6, magnesium, zinc or equivalents thereof. The composition further comprises folic acid and vitamin B6 as well as SAMe, choline, betaine and/or copper. Specifically, the fatty acids are omega-3 and omega-6 fatty acids wherein omega-3 fatty acids are selected from eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) and the omega-6 fatty acids are selected from arachidonic acid (ARA) and dihomogamma linolenic acid (DGLA) and the phospholipids comprise phosphatidylcholine, phosphatidylethanolamine and phosphatidylserine

Sagami teaches compositions for improving lipids in the blood, arteriosclerosis and vascular diseases comprising DHA, phosphatidylcholine, phosphatidyl ethanolamine and/or phosphatidylserine (abstract).

Horrobin teaches compositions for treating/preventing hypertension, coronary heart disease and peripheral vascular disease that are enriched with DGLA and ARA, EPA or DHA (abstract).

Hashim teaches compositions for preventing vascular disorders comprising vitamin B6, betaine, choline, vitamin B12 and folic acid (abstract).

The above references do not teach each of the ingredients together in a single composition administered in a method for treating/preventing vascular and related disorders. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose. In addition, it would have been obvious to one of ordinary skill in the art to use the combination in a method for treating/preventing vascular disorders because they were each well known for the claimed function. Moreover, at the time if the invention, one of ordinary skill in the art would have been motivated to combine the instant ingredients with a reasonable expectation for successfully treating/preventing vascular disorders.

8. Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sagami (1998), Horrobin (1996), Hashim (1995) and Sauvage et al. (US 5401730).

Applicant claims a method for treating and/or preventing vascular disorders and/or secondary disorders associated therewith, the method comprising administering a composition comprising (a) long chain polyunsaturated fatty acids, (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine, (c) one or more compounds selected from folate, vitamin B12, B6, magnesium, zinc or equivalents thereof and (d) citrate.

Sagami teaches compositions for improving lipids in the blood, arteriosclerosis and vascular diseases comprising DHA, phosphatidylcholine, phosphatidyl ethanolamine and/or phosphatidylserine (abstract).

Horrobin teaches compositions for treating/preventing hypertension, coronary heart disease and peripheral vascular disease that are enriched with DGLA and ARA, EPA or DHA (abstract).

Hashim teaches compositions for preventing vascular disorders comprising vitamin B6, betaine, choline, vitamin B12 and folic acid (abstract).

Sauvage et al. teaches compositions for treating thrombus formation, atherosclerosis and cardiovascular diseases comprising citric acid (abstract). The composition is disclosed to exhibit synergistic effects in inhibiting platelet aggregation (abstract). Sauvage additionally teaches methods for reducing vascular disorders using the composition (abstract).

The above references do not teach each of the ingredients together in a single composition administered in a method for treating/preventing vascular and related disorders. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit, as disclosed by

the cited references above, since each is well known in the art for their claimed purpose. In addition, it would have been obvious to one of ordinary skill in the art to use the combination in a method for treating/preventing vascular disorders because they were each well known for the claimed function. Moreover, at the time if the invention, one of ordinary skill in the art would have been motivated to combine the instant ingredients with a reasonable expectation for successfully treating/preventing vascular disorders.

9. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sagami (1998), Horrobin (1996), Hashim (1995), Bozoky (1997) and Ponomareva (1995).

Applicant claims a method for treating and/or preventing vascular disorders and/or secondary disorders associated therewith, the method comprising administering a composition comprising (a) long chain polyunsaturated fatty acids, (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine, (c) one or more compounds selected from folate, vitamin B12, B6, magnesium, zinc or equivalents thereof and (d) hypericin and/or extract of Withania somnifera.

Sagami teaches compositions for improving lipids in the blood, arteriosclerosis and vascular diseases comprising DHA, phosphatidylcholine, phosphatidyl ethanolamine and/or phosphatidylserine (abstract).

Horrobin teaches compositions for treating/preventing hypertension, coronary heart disease and peripheral vascular disease that are enriched with DGLA and ARA, EPA or DHA (abstract).

Hashim teaches compositions for preventing vascular disorders comprising vitamin B6, betaine, choline, vitamin B12 and folic acid (abstract).

Bozoky et al. teaches a mixture for reducing LDL cholesterol comprising extract of St. John's wort (abstract). Ponomareva et al. teaches a composition for reducing blood pressure comprising St. John's wort (abstract).

The above references do not teach each of the ingredients together in a single composition administered in a method for treating/preventing vascular and related disorders. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose. In addition, it would have been obvious to one of ordinary skill in the art to use the combination in a method for treating/preventing vascular disorders because they were each well known for the claimed function. Moreover, at the time if the invention, one of ordinary skill in the art would have been motivated to combine the instant ingredients with a reasonable expectation for successfully treating/preventing vascular disorders.

10. Claims 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sagami (1998), Horrobin (1996), Hashim (1995), Cade et al. (1989) and Ogawa (1995).

Applicant claims a method for treating and/or preventing vascular disorders and/or secondary disorders associated therewith, the method comprising administering a composition comprising (a) long chain polyunsaturated fatty acids, (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and

phosphatidylethanolamine, (c) one or more compounds selected from folate, vitamin B12, B6, magnesium, zinc or equivalents thereof and (d) tryptophan, an analog thereof or a protein containing tryptophan.

Sagami teaches compositions for improving lipids in the blood, arteriosclerosis and vascular diseases comprising DHA, phosphatidylcholine, phosphatidyl ethanolamine and/or phosphatidylserine (abstract).

Horrobin teaches compositions for treating/preventing hypertension, coronary heart disease and peripheral vascular disease that are enriched with DGLA and ARA, EPA or DHA (abstract).

Hashim teaches compositions for preventing vascular disorders comprising vitamin B6, betaine, choline, vitamin B12 and folic acid (abstract).

Cade et al. teaches a composition and method for treating hypertension, cardiac hypertrophy and atherosclerosis, comprising administration of L-tryptophan (abstract).

Ogawa teaches a composition for treating hyperlipidemia comprising tryptophan (abstract).

The above references do not teach each of the ingredients together in a single composition administered in a method for treating/preventing vascular and related disorders. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose. In addition, it would have been obvious to one of ordinary skill in the art to use the combination in a method for treating/preventing vascular disorders because they were each well known for the

claimed function. Moreover, at the time if the invention, one of ordinary skill in the art would have been motivated to combine the instant ingredients with a reasonable expectation for successfully treating/preventing vascular disorders.

11. Claims 1 and 9 – 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sagami (1998), Horrobin (1996), Hashim (1995) and Bland (US 5922704).

Applicant claims a method for treating and/or preventing vascular disorders and/or secondary disorders associated therewith, the method comprising administering a composition comprising (a) long chain polyunsaturated fatty acids, (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine and (c) one or more compounds selected from folate, vitamin B12, B6, magnesium, zinc or equivalents thereof. The composition further comprises SAMe, choline, betaine and/or copper wherein the weight ratio of zinc to copper is between 5 – 12, one or more selected from carnitine, vitamin B1, B5, coenzyme Q10 and functional analogs thereof, and one or more antioxidants selected from vitamin C, E, lipoic acid, selenium salt and carotenoids.

Sagami teaches compositions for improving lipids in the blood, arteriosclerosis and vascular diseases comprising DHA, phosphatidylcholine, phosphatidyl ethanolamine and/or phosphatidylserine (abstract).

Horrobin teaches compositions for treating/preventing hypertension, coronary heart disease and peripheral vascular disease that are enriched with DGLA and ARA, EPA or DHA (abstract).

Hashim teaches compositions for preventing vascular disorders comprising vitamin B6, betaine, choline, vitamin B12 and folic acid (abstract).

Bland teaches nutritional supplements comprising omega 3 and omega 6 fatty acids, magnesium, zinc, copper and selenium (abstract). Specifically, Bland teaches that the fatty acids are useful for maintaining cardiovascular health and cholesterol levels (col.2 line28-32). Bland further teaches that magnesium (col.2 line 49-56), zinc, copper (col.2 line 62-68), vitamins B6, B12, folate (folic acid) (col.3 line20-29), vitamins C, B1 and E (col.3 line 35-40) are involved in maintaining cardiovascular health, function and support as well as effectively prevent/treat vascular disorders and cardiac risk. Finally, Bland teaches a ratio of zinc to copper of about 5:1 (abstract).

The above references do not teach each of the ingredients together in a single composition administered in a method for treating/preventing vascular and related disorders. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose. In addition, it would have been obvious to one of ordinary skill in the art to use the combination in a method for treating/preventing vascular disorders because they were each well known for the claimed function. Moreover, at the time if the invention, one of ordinary skill in the art would have been motivated to combine the instant ingredients with a reasonable expectation for successfully treating/preventing vascular disorders.

12. Claims 1 and 11 – 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sagami (1998), Horrobin (1996), Hashim (1995) and Cavazza (5753703).

Applicant claims a method for treating and/or preventing vascular disorders and/or secondary disorders associated therewith, the method comprising administering a composition comprising (a) long chain polyunsaturated fatty acids, (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine and (c) one or more compounds selected from folate, vitamin B12, B6, magnesium, zinc or equivalents thereof. The composition further one or more selected from carnitine, vitamin B1, B5, coenzyme Q10 and functional analogs thereof, and one or more antioxidants selected from vitamin C, E, lipoic acid, selenium salt and carotenoids.

Sagami teaches compositions for improving lipids in the blood, arteriosclerosis and vascular diseases comprising DHA, phosphatidylcholine, phosphatidyl ethanolamine and/or phosphatidylserine (abstract).

Horrobin teaches compositions for treating/preventing hypertension, coronary heart disease and peripheral vascular disease that are enriched with DGLA and ARA, EPA or DHA (abstract).

Hashim teaches compositions for preventing vascular disorders comprising vitamin B6, betaine, choline, vitamin B12 and folic acid (abstract).

Cavazza et al. teaches compositions for treating and preventing lipid metabolism disorders and cardiovascular disorders comprising omega 3 fatty acids (DHA and EPA, see col.1 line10-16) and carnitine (abstract). Cavazza specifically teaches the compositions are useful for treating/preventing vascular disorders, atherosclerotic and thromboembolic disorders (col.1 line

15-20). In addition, Cavazza teaches a synergistic effect between carnitines and omega 3 fatty acids (col.5 line 5-10). Other vitamins and antioxidants are included in the compositions to include alpha-tocopherol (vitamin E), beta carotene, selenium, zinc and magnesium (col.6 line 55 – col.7 line 15).

The above references do not teach each of the ingredients together in a single composition administered in a method for treating/preventing vascular and related disorders. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose. In addition, it would have been obvious to one of ordinary skill in the art to use the combination in a method for treating/preventing vascular disorders because they were each well known for the claimed function. Moreover, at the time if the invention, one of ordinary skill in the art would have been motivated to combine the instant ingredients with a reasonable expectation for successfully treating/preventing vascular disorders.

13. Claims 1 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sagami (1998), Horrobin (1996), Hashim (1995), Yanai (1998) and He (2000).

Applicant claims a method for treating and/or preventing vascular disorders and/or secondary disorders associated therewith, the method comprising administering a composition comprising (a) long chain polyunsaturated fatty acids, (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and

phosphatidylethanolamine, (c) one or more compounds selected from folate, vitamin B12, B6, magnesium, zinc or equivalents thereof and (d) ginkgo biloba extract.

Sagami teaches compositions for improving lipids in the blood, arteriosclerosis and vascular diseases comprising DHA, phosphatidylcholine, phosphatidyl ethanolamine and/or phosphatidylserine (abstract).

Horrobin teaches compositions for treating/preventing hypertension, coronary heart disease and peripheral vascular disease that are enriched with DGLA and ARA, EPA or DHA (abstract).

Hashim teaches compositions for preventing vascular disorders comprising vitamin B6, betaine, choline, vitamin B12 and folic acid (abstract).

Yanai teaches compositions for treating vascular disorders, dementia syndromes, and hypertension comprising ginkgo extract (abstract). In addition, He teaches extracts of ginkgo are used to prevent and cure hyperlipidemia, arteriosclerosis and vascular diseases (abstract).

The above references do not teach each of the ingredients together in a single composition administered in a method for treating/preventing vascular and related disorders. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose. In addition, it would have been obvious to one of ordinary skill in the art to use the combination in a method for treating/preventing vascular disorders because they were each well known for the claimed function. Moreover, at the time if the invention, one of ordinary skill in the art would

have been motivated to combine the instant ingredients with a reasonable expectation for successfully treating/preventing vascular disorders.

14. Claims 1 and 15 – 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sagami (1998), Horrobin (1996), Hashim (1995), Sauvage et al. (US 5401730), Bland (US 5922704), Bozoky (1997) and Ponomavera (1995).

Applicant claims a method for treating and/or preventing vascular disorders and/or secondary disorders associated therewith, the method comprising administering a composition comprising (a) long chain polyunsaturated fatty acids, (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine and (c) one or more compounds selected from folate, vitamin B12, B6, magnesium, zinc or equivalents thereof. Specifically, the composition comprises folate, citrate and hypericin and/or Withania somnifera extract and administration in daily doses of 120 mg long chain fatty acids, 200 mg phopholipids, 200 micrograms folate acid, 500 mg citrate and 0.1 mg hypericin and/or 100 mg Withania somnifera extract. More specifically, the composition comprises at least 20 mg EPA, 50 mg DHA, 50 mg ARA, 200 mg phopspholipids, 200 micrograms folate, 0.2 mg hypericin and/or 500 mg Withania somnifera extract, 100 mg magnesium, 5 mg zinc, 2 mg vitamin B6, 2 micrograms vitamin B12 and 1 g citrate.

Sagami teaches compositions for improving lipids in the blood, arteriosclerosis and vascular diseases comprising DHA, phosphatidylcholine, phosphatidyl ethanolamine and/or phosphatidylserine (abstract).

Horrobin teaches compositions for treating/preventing hypertension, coronary heart disease and peripheral vascular disease that are enriched with DGLA and ARA, EPA or DHA (abstract).

Hashim teaches compositions for preventing vascular disorders comprising vitamin B6, betaine, choline, vitamin B12 and folic acid (abstract).

Sauvage et al. teaches compositions for treating thrombus formation, atherosclerosis and cardiovascular diseases comprising citric acid (abstract). The composition is disclosed to exhibit synergistic effects in inhibiting platelet aggregation (abstract). Sauvage additionally teaches methods for reducing vascular disorders using the composition (abstract).

Bland teaches nutritional supplements comprising omega 3 and omega 6 fatty acids, magnesium, zinc, copper and selenium (abstract). Specifically, Bland teaches that the fatty acids are useful for maintaining cardiovascular health and cholesterol levels (col.2 line28-32). Bland further teaches that magnesium (col.2 line 49-56), zinc, copper (col.2 line 62-68), vitamins B6, B12, folate (folic acid) (col.3 line20-29), vitamins C, B1 and E (col.3 line 35-40) are involved in maintaining cardiovascular health, function and support as well as effectively prevent/treat vascular disorders and cardiac risk.

Bozoky et al. teaches a mixture for reducing LDL cholesterol comprising extract of St. John's wort (abstract).

Ponomareva et al. teaches a composition for reducing blood pressure comprising St. John's wort (abstract).

The above references do not teach each of the ingredients together in a single composition administered in a method for treating/preventing vascular and related disorders.

However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose. In addition, it would have been obvious to one of ordinary skill in the art to use the combination in a method for treating/preventing vascular disorders because they were each well known for the claimed function. Although the references so not teach the specific amounts as claimed, it would have been obvious to one of ordinary skill in the art to optimize volumes of effective ingredients as it was routine practice in the art at the time the claimed invention was made. Moreover, at the time if the invention, one of ordinary skill in the art would have been motivated to combine the instant ingredients with a reasonable expectation for successfully treating/preventing vascular disorders.

15. Claims 1 and 17 – 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brigham (WO 97/39759), Bridgeman (US 6200607) and Sakai et al. (US 5965413).

Applicant claims a method for treating and/or preventing vascular disorders and/or secondary disorders associated therewith, the method comprising administering a composition comprising (a) long chain polyunsaturated fatty acids, (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine and (c) one or more compounds selected from folate, vitamin B12, B6, magnesium, zinc or equivalents thereof. Specifically, the method is for treatment and/or prevention of depression or related disorders to include bipolar or unipolar depression,

depression related to menstruation, menopause, schizophrenia, ADHD, anxiety, insomnia, seasonal affective disorder, dementia or Parkinson's disease.

Brigham teaches a method for treating bipolar disorder comprising administering omega-3 fatty acids (abstract). Specifically, Brigham teaches phosphatidylcholine and omega-3 fatty acids are administered to treat bipolar patients (p.1 line22-28).

Bridgeman teaches a composition for treating Parkinson's disease or depression, the composition comprising vitamin B6, folate and zinc (abstract).

Sakai et al. teaches phosphatidylserine is effective for prevention and treatment of Parkinson's disease and dementia (col.1 line 5-15).

The above references do not teach each of the ingredients together in a single composition administered in a method for treating/preventing the aforementioned disorders. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose. In addition, it would have been obvious to one of ordinary skill in the art to use the combination in a method for treating/preventing such disorders because they were each well known for the claimed function. Moreover, at the time if the invention, one of ordinary skill in the art would have been motivated to combine the instant ingredients with a reasonable expectation for successfully treating/preventing depression or related disorders.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ruth A. Davis; rad
February 5, 2002